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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/509,910	04/03/00	SEBALD	W LEA32545

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HM12/1023

EXAMINER
SEHARASEYON, J

ART UNIT	PAPER NUMBER
1647	11

DATE MAILED: 10/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/509,910

Applicant(s)

SEBALD, WALTER

Examiner

Jegatheesan Seharaseyon

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 5-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 and 3. 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election of Group I, claims 1-4, drawn to the proteins in Paper No.10 (7/30/01) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a)).

Claims 5-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10 (7/30/01).

Specification

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3a. Claims 1-4 are rejected as vague and indefinite for reciting the term "mutein", because the specification does not clearly define the term "mutein". The muteins described could be deletion, substitution, addition of a single amino acid or more than one amino acid.

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3b. Claim 1 is rejected as vague and indefinite for reciting the term "muteins", because it is unclear if it is referring multiple mutations on hIL-4.

3c. The term "reduced affinity" in claim 1 is a relative term which renders the claim indefinite. The term "reduced affinity" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. Claim 1 is rejected insofar as it depends on rejected claim 2.

3d. The term "altered specificity" in claim 1 is a relative term which renders the claim indefinite. The term "altered specificity" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. Claim 1 is rejected insofar as it depends on rejected claim 2.

3e. Claim 2 is rejected as being indefinite because the claim recites "having replacement of a naturally occurring amino acid in the A-helix of hIL-4 by another amino acid". It is unclear how the replacement of naturally occurring amino acid will affect the functional attributes of IL-4. Claim 2 is rejected insofar as it depends on rejected claim 3

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4a. The instant claims (1-4) encompass mutein proteins that have reduced affinity and/or an altered specificity to the γ subunit of the IL-4 receptor and/or HIL-13R α

subunit of the hIL-4 receptor. However, the instant specification only discloses the muteins disclosed in Table 1 and 2 which meets the limitations of these claims. The instant specification provides no guidance as how to modify the disclosed protein and obtain a protein which has the reduced affinity and/or altered. The specification provides no guidance as to which amino acids (i.e. structural elements) of the native proteins are critical to the biological activity which is recited in the claims. Without this type of guidance, the skilled artisan does not have a reasonable expectation of mutating the hIL-4 and obtaining a functional protein that retains an altered biological activity of the native protein. One may argue screening for bioactivity could be done, however, this is basically a "wish to know" and the standard for an enabling disclosure is not one of making and testing. Unless one has a reasonable expectation that any one material embodiment of the claimed invention would be more likely than not to function in the manner disclosed or the instant specification provides sufficient guidance to permit one to identify those embodiments which are more likely to work than not without actually making and testing them, then the instant application does not support the breadth of the claims.

A review of *In re Wands* clearly points out the factors to be considered in determining whether a disclosure would require undue experimentation and include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. All of these

factors are considerations when determining the enablement of an invention. The claims encompass a limitless number of embodiments because they recite no structural limitations on the hIL-4 protein. The specification provides no guidance as to amino acid positions and/or regions which are critical to the recited bioactivity of hIL-4. The claims encompass molecules with reduced affinity and/or an altered specificity, however, one of ordinary skill in the art would not reasonably expect that a molecule that meets this limitation of the claims to be sufficient for biological activity. The claims are exceedingly broad because they only require reduced affinity and/or an altered specificity. In addition, although the skill in the art is known to be high, the results of mutating amino acids to produce a functional protein is highly unpredictable. Therefore, in light of this analysis, one would reasonably conclude that the breadth of the instant claims is not commensurate in scope with the specification, absent evidence to the contrary.

4b. Claim 1 is a single means claims in that they recite "analogue thereof", but the specification only discloses muteins of Table 1 and 2. MPEP 2164.08(a) defines a single means claim as a claim which covered every conceivable means for achieving the stated purpose when the specification disclosed at most only those means known to the inventor. This type of claim was held to be nonenabling for the scope of the claim in *In re Hyatt*, 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983) because the specification disclosed at most only those means known to the inventor. When claims depend on a recited property (i.e. reduced affinity and/or an altered specificity), a fact situation

comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. This appears to be the instant case and the claims are not commensurate in scope with the specification.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5a. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. (1997).

The instant invention is directed to hIL-4 mutein proteins that have reduced affinity and/or an altered specificity to the γ subunit of the IL-4 receptor and/or HIL-13R α subunit of the hIL-4 receptor.

Wang et al. teaches production of the muteins of IL-4 Q8A, Q8R, I11A, K12S, K12E, N15A and N15D in E.coli (Table 1 and 2). Reduced affinity and/or an altered specificity to the γ subunit of the IL-4 receptor and/or HIL-13R α subunit of the hIL-4 receptor is inherent to the mutations disclosed. Therefore, the disclosure of Wang et al. anticipates claims 1-3.

5b. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Kruse et al. (1993).

The instant invention is directed to hIL-4 mutein proteins that have reduced affinity and/or an altered specificity to the γ subunit of the IL-4 receptor and/or HIL-13R α subunit of the hIL-4 receptor.

Kruse et al. teaches production of the muteins of IL-4 R121D, K123D, Y124D, S125D in E.coli (Table 1). Reduced affinity and/or an altered specificity to the γ subunit of the IL-4 receptor and/or HIL-13R α subunit of the hIL-4 receptor is inherent to the mutations disclosed. Therefore, the disclosure of Kruse et al. anticipates claims 1 and 4.


6. No claims are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


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